Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Ice Sucking on Ginger Extract on Control of Chemo Nausea

Protocol summary

Study aim
Effect of Ice Sucking on Ginger Extract on Control of Chemo Nausea and vomiting
Design
Clinical trial with a control group, double-blind, randomized on 80 patients using quadruple random blocks
Settings and conduct
The current study is a randomized clinical trial, which will be conducted with the aim of the effect of ginger ice sucking on nausea and vomiting during chemotherapy, and the patients of the oncology department of Ganjovian Hospital (80 patients) will be divided into two control and intervention groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria : Age older than 20 years old; definitive cancer diagnosis by oncologist; history of receiving at least one course of chemotherapy; history of experiencing nausea and vomiting. Exit criteria: Patient dissatisfaction; inaccuracy in filling the questionnaires; using anti-emetic drugs; suffering from gastrointestinal diseases.
Intervention groups
The intervention group is cancer patients undergoing chemotherapy who receive the ice ginger. The control group consists of cancer patients undergoing chemotherapy who receive routine treatment
Main outcome variables
Nausea and vomiting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170607034381N8**
Registration date: **2022-10-26, 1401/08/04**
Registration timing: **prospective**

Last update: **2022-10-26, 1401/08/04**
Update count: **0**
Registration date
2022-10-26, 1401/08/04

Registrant information
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Ferdos Pelarak
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-05, 1401/08/14
Expected recruitment end date
2023-02-03, 1401/11/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Ice Sucking on Ginger Extract on Control of Chemo Nausea

Public title
Effect of ginger ice in nausea and vomiting caused by chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age older than 20 years old Definitive diagnosis of

cancer by an oncologist History of receiving at least one course of chemotherapy, history of experiencing nausea and vomiting

Exclusion criteria:

Use of antiemetic drugs separate from the routine of other patients Having a digestive disease

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **80**

Cancer patient

Randomization (investigator's opinion)

Randomized

Randomization description

By using the random allocation software, the patients will be randomly assigned to the intervention or placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and researcher do not know which group the people are placed in. By assigning container A and B, the samples do not know whether they are receiving a placebo or the original drug. The statistician will receive the questionnaires anonymously and in the form of A and B and will not know which is the intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gachsaran Islamic Azad University

Street address

Islamic Azad University of Gachsaran

City

Gachsaran

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7581863876

Approval date

2021-12-15, 1400/09/24

Ethics committee reference number

IR.IAU.IAUG.REC.1400.002

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

Before intervention and after Chemotherapy

Method of measurement

Rhodes index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During chemotherapy, 40 pieces of ice containing ginger extract, each piece of ice is 1 cc, will be given to the patient at 1-minute intervals from 5 minutes before the start of chemotherapy to the end of chemotherapy.

Category

Treatment - Drugs

2

Description

Control group: Receive Placebo 40 pieces of ice each piece of ice is 1cc with out ginger extract

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Ganjavian hospital

Full name of responsible person

Fateme Mohtadi
Street address
Gangavian Hospital, Andimesh road to Dezful
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ali Ershadi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ferdos Pelarak
Position
instructor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Fateme Mohtadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals
When the data will become available and for how long
12 months after the results are published
To whom data/document is available
Researchers working in scientific and academic institutions
Under which criteria data/document could be used
According to the terms and conditions of Dezful Azad University, the data can be used
From where data/document is obtainable
Fateme Mohtadi fatememohtadi713@gmail.com
What processes are involved for a request to access data/document
Written request and consent of the Executor of the project and colleagues
Comments